Summary of the NELAC Accrediting Authority Committee Teleconference November 14, 1996

The National Environmental Laboratory Accreditation Conference (NELAC) Accrediting Authority Committee met by teleconference from 12:30 to 2:30 pm Eastern Standard Time (EST) on Thursday, November 14, 1996. The meeting was led by Committee Chair, Mr. John Anderson, Division Manager of the State of Illinois Environmental Protection Agency (IL-EPA). A list of action items is given in Attachment A. A list of Committee members/invited guests is given in Attachment B. A copy of the teleconference agenda is given in Attachment C.

INTRODUCTION

Mr. Anderson opened the meeting with a discussion of the minutes of the October 23, 1996, teleconference. A typographical error was noted in the e-mail address of Ms. Mary Ann Feige. This will be corrected prior to submitting the minutes for distribution electronically on the NELAC bulletin board: http://ttnwww.rtpnc.epa.gov. Mr. Anderson reminded the Committee that the deadline for completion of the draft of Chapter 6 is December 20, 1996.

Mr. Anderson announced that Dr. Charles Brokopp will no longer be an official member of the NELAC Accrediting Authority Committee because he currently serves on the NELAC Board of Directors. Membership on the Board and a Committee is mutually exclusive. Ms. Feige of USEPA, Cincinnati, will replace him. This will leave the Committee with one vacancy to be filled from the private laboratory sector.

REVIEW OF ACTION ITEMS IN THE MINUTES OF THE OCTOBER 23, 1996, TELECONFERENCE

Mr. John Anderson will write a letter to Ms. Jeanne Mourrain, NELAP Director to:

- clarify the role of Federal agencies as NELAP-recognized accrediting authorities,
 and
- determine the resource support for accrediting authority auditors.

Ms. Mourrain agreed that Federal agencies do not have a significant role as accrediting authorities because most accrediting authorities will be States. For example, the States of Illinois and Kansas accredit Federal laboratories in their States. However, at this time Ms. Mourrain did not want to exclude Federal agencies from becoming NELAP-recognized accrediting authorities.

There is very little chance of having the NELAP assessment teams charged with reviewing applications for NELAP recognition of accrediting authorities expanded to three auditors (two Federal and one State). Most likely, there will be one Federal auditor and one State auditor. Assuming that Federal agencies don't become accrediting authorities, only about 55 NELAP-recognized accrediting authorities are anticipated.

With only 55 NELAP-recognized accrediting authorities, one to two work years from individuals assigned to NELAP headquarters should be sufficient to carry out the application review and audit functions in a timely manner. Because a comprehensive paper audit is required to precede the on-site audit, the NELAP assessment team members would not necessarily review each detail of an accrediting authority's program during the on-site audit. Rather, the team would choose elements of the accrediting authority's program for inspection. Further, it was acknowledged that it would be unrealistic to require assessment team members to accompany an accrediting authority's employees on an on-site audit of a laboratory. There is no commitment that USEPA Regional staff would be utilized on audit teams.

Mr. Anderson will redraft Section 6.1a to reference ISO 58, and its applicability to international approval and acceptability.

Section 6.1 has been expanded to state that all requirements of ISO/IEC (International Organization for Standardization/International Electrotechnical Commission) will be met by a NELAP-recognized accrediting authority. Chapter 6 clearly states that a NELAP-recognized accrediting authority's program must meet all the requirements of NELAC Chapters 1 through 6. Thus, all ISO requirements will be met.

Ms. Roxanne Robinson and Dr. Jeff Flowers will provide a list of deviations in Chapter 6 and ISO Guide 58.

The list has been completed and double-checked. Because of insufficient time, the draft Chapter 6 has not been completely revised to address ISO 58 deviations. Additions/changes will be incorporated by Mr. Anderson and Ms. Jeri Long within one week.

Mr. Anderson will provide a summary of ISO Guide 61 and distribute it to teleconference participants.

ISO Guide 61 was distributed to teleconference participants.

Mr. Bob Wyeth will redraft Section 6.2c to clarify unconditional reciprocity.

Mr. Wyeth has completed the revision of this section and discussed his changes with Ms. Aurora Shields.

The next draft will contain terminology to explain how a Federal or State accrediting authority will recognize a third-party accreditor.

This has been included in the draft and will be discussed as the Committee systematically reviews the draft.

The NELAC Accrediting Authority Committee members will revise (with proposed terminology) the double-spaced version of Chapter 6 either electronically (underline/strikeout) or by hand and submit their revisions to Mr. Anderson for incorporation into the new draft.

Ms. Shields submitted revisions and noted some typographical errors.

Mr. Anderson will explore the cost of teleconference calls to schedule either additional teleconferences or face-to-face meetings to meet deadlines for submission.

Additional teleconferences were arranged through the Federal system with the help of Dr. Ted Coopwood. A list of the additional teleconferences was e-mailed to teleconference participants.

SYSTEMATIC REVIEW OF CHAPTER 6

A revised version of Chapter 6 was e-mailed to teleconference participants with new text identified by underlining and deleted text identified by strikeover. All subsections refer to the numbering as it existed in the Revision 1, November 13, 1996 draft of Chapter 6.

Section 6.1 -- Introduction

The Committee concurred that the revised Section 6.1 clearly stated that a NELAP-recognized accrediting authority would comply with virtually all of ISO Guide 58 requirements.

Section 6.2 -- General Provisions

6.2 b)

The underlined text was approved because it was unrealistic to expect that a State might have only one agency to serve as an accrediting authority. The use of singular and plural forms of "NELAP-recognized accrediting authority" was discussed. The Committee agreed the plural form, "authorities," was appropriate.

6.2 c)

During the October 23, 1996, teleconference, Committee members expressed concern over the use of the term "unconditional" reciprocity. Mr. Wyeth rewrote and proposed a new Section 6.2 (b) as follows to address that concern:

"A NELAP-recognized accrediting authority shall grant unconditional reciprocity to all other NELAP-recognized accrediting authorities for appropriate and applicable fields/categories of testing for which the accrediting authority is recognized. Reciprocity is offered without loss of the accrediting authority's right to access and collect fees from the laboratories ultimately utilizing said authority."

Mr. Wyeth added the following comment to his revision of Section 6.2 c: "The concern over 'supplemental' requirements of a given state (accrediting authority) need not be addressed here. If the given supplemental requirement of the method/test is so significant as to necessitate special

consideration, the accrediting authority can choose not to be accredited for that method or field of testing." Mr. Wyeth's revision of Section 6.2 and his comment will be faxed to the teleconference recording secretary.

The Committee continued to discuss the importance of the use of "unconditional" reciprocity. Mr. Anderson reminded the Committee that at the NELAC meeting in Washington, DC, Dr. Bob Stevens, Past Chair, NELAC Board of Directors, emphasized that the entire NELAP program would be undermined without acceptance of unconditional reciprocity. The Committee discussed reciprocity relative to minimal requirements, rather than identical requirements, for laboratory performance. The relevance of method/analyte parameter or satisfactory laboratory audit and performance evaluation to reciprocity was also discussed. Ms. Shields agreed to provide documents that would explain how Kansas handles reciprocal agreements. Mr. Anderson reiterated private laboratory concerns that unconditional reciprocity be clearly defined in the NELAC standards. In addition Mr. Anderson recalled conversations with Dr. Charles Hartwig, Chair, NELAC Board of Directors, stating NELAC's position that standards must be the same across the country or NELAP will not succeed. A suggestion was made that if a State does not have the option of using the rules it establishes for laboratories conducting laboratory work in that State, it is likely that the State will develop two different accreditation programs: 1) to meet NELAP requirements, and 2) to meet State requirements. Mr. Anderson questioned whether much of this issue couldn't be resolved by USEPA programs becoming more congruent with their laboratory data requirements. The use of the term "unconditional" was still unresolved; Mr. Anderson will talk with Dr. Hartwig for guidance.

6.2 e) 3)

The intent of the section is to establish fee-based criteria for NELAP accreditation. The financial basis of support for accreditation programs was discussed relative to programs in North Carolina and New York. North Carolina programs are totally supported by fees, and there is no anticipation of a change in this support. A similar situation exists in Illinois. New York program charges are based on the number of samples analyzed for the State of New York. The Committee considered that the term "financial conditions" was acceptable, but notes were made that this section may be rewritten before the next draft is submitted to the Committee.

6.2 g)

This section was acceptable as written.

6.2 h) 2), 3), and 4)

The sections were taken from ISO 58 and considered to be acceptable as rewritten.

Section 6.3 -- Application for NELAP Recognition 6.3.1 -- Written Application for NELAP Recognition b) 4)

The section was written to provide specific criteria for liability and worker's compensation claims because ISO 58 language was nebulous, specifying only that an accrediting authority must have "adequate arrangements" to cover liability issues. In order to address the question of adequacy of

insurance, the section requires each NELAP-recognized accrediting authority to have the same arrangements to cover liabilities and worker's compensation claims as all other units in the agency where the accrediting authority is located. The Committee discussed whether the language would be adequate for Federal agencies such as the Department of Defense (DOD), and concluded that the Federal agencies have their own liability insurance.

b) 9) and 10)

A typographical error was identified in b) 9). The citation should be 6.3.3(d)(19)(B). The inclusion of citation 6.3.3(d)(19)(B) was approved because of its appropriateness to describe the organizational structure for an external assessment body. The Committee concurred that the accrediting authority documentation should be detailed (i.e., provide names and titles of staff members) in order to provide the audit team with as much information as possible to streamline the on-site process. It was suggested that a mechanism used by the American Association of Laboratory Accreditation (A2LA) be followed where a summary of names is attached to the accrediting authority's application and additions/changes to this summary are revised in a timely fashion. A new Subsection 6.3.1(e)(5) will be added to require this notification.

b) 11)

A suggestion was made to change the term "performance evaluation samples" to "proficiency testing study samples" to be consistent with terminology used in the NELAC Proficiency Testing (PT) Committee. The terminology has been changed.

b) 16) B)

The application should include documentation of the time frame the accrediting authority requires to accredit a laboratory. The Committee discussed the relevance of including "average, mean, and maximum" times from the point that the application is filed until accreditation is granted. A suggestion was made to include a table that indicates the accrediting authority is compliant by granting or declining accreditation within the nine-month limitation (from submittal to final action) established by NELAC. The Committee agreed that the table should include a list of laboratories accredited, with dates of initial submittal of application and final action. This table must be submitted with the application. This section will be rewritten to require this information be included in the application for NELAP recognition.

b) 20)

The Committee agreed that the name and job title of individuals authorized to sign the accrediting certificates should be included.

b) 21)

The entire section was included because of Section 4.2k of the ISO Guide 58 requirement that stated, "The organization of the accrediting body shall establish one or more technical committees, each within its scope for advising the accrediting authority." Questions about the necessity and function of a technical advisory committee were raised, with the function described as updating rules and regulations of the accrediting authority. The State of Kansas does not require a technical advisory committee, whereas the State of New York does rely on technical

advisory committees. Illinois currently has a functioning advisory committee. Mr. Wyeth, who serves on the Chemical Advisory Committee for the State of New York, suggested that Chapter 6 terminology be stated as: "NELAC encourages the accrediting authorities to establish technical advisory committees." In this way the accrediting authority would have the option of incorporating a technical advisory committee, but not the requirement to do so. Laboratories accredited by the accrediting authority could also request that the accrediting authority establish a technical advisory committee. Consensus was reached that NELAC should not require the establishment of advisory committees, but rather encourage their formation. Thus, Subsection 6.3.1(b)(21) will be deleted. Subsection 6.3.3(d)(9) will be moved to 6.2(k) with its wording changed to reflect encouragement of advisory committee formation rather than requiring the formation of such committees.

The proposed incorporation of Section (b)(21) and corresponding Section 6.3.3(d)(9) raised questions about the reconciliation of NELAC and ISO requirements, particularly the question of why NELAC requirements must be identical to ISO requirements. Although the portions of Chapter 6 that incorporate ISO requirements were not taken verbatim from ISO Guide 58, the intent was to incorporate the requirements of ISO Guide 58. Mr. Anderson reminded the Committee that at the October 23, 1996, teleconference, the consensus was that Chapter 6 be "ISO compliant," rather than "ISO-like." Subsequent to the October 23, 1996 meeting, Ms. Robinson and Dr. Flowers reviewed the previous draft of Chapter 6 and identified each deviation from ISO Guide 58. It was agreed that Mr. Anderson and Ms. Long will review the Robinson/Flowers list and use their professional judgment to incorporate relevant ISO 58 requirements in Chapter 6. This should result in virtually all of ISO Guide 58 being included in NELAC, but not necessarily every detail.

c)
The appropriateness of the title of Chief Executive Officer (CEO) for an accrediting authority (State) was discussed. A suggestion was made that a consistent job title, such as Director, could be applicable to all States. Mr. Wyeth will suggest an appropriate title and submit it to Mr. Anderson to be incorporated into the revision of this section.

d)

The Committee approved the section requiring NELAP to be responsible for renewal notices to the accrediting authorities. NELAP must inform an accrediting authority 90 days prior to the expiration of the authority's NELAP recognition.

CONCLUSION

Mr. Anderson concluded the teleconference by reviewing the action items for the next teleconference, scheduled for Wednesday, November 20, 1996, from 1:00 to 3:00 pm Eastern Standard Time (EST). By the time of the November 20th teleconference, all agreed-upon revisions will be made through page 9 of the draft and distributed to the Committee members. The Committee was reminded of the deadline of December 20, 1996, for revisions in the draft of Chapter 6 to be finalized.

ACTION ITEMS NELAC Accrediting Authority Committee Teleconference November 14, 1996

Item No.	Item Description	Date Completed
1	Emily Williams will make corrections in the spelling of "feige" in the e-mail address of Mary Ann Feige in the minutes of the October 23, 1996, teleconference.	
2	All revisions through page 9 of Chapter 6 will be made by the November 20, 1996, teleconference.	
3	John Anderson will discuss the issue of "unconditional reciprocity" with Charles Hartwig.	
4	Aurora Shields will send exemplary information to describe how the State of Kansas treats reciprocity.	
5	Bob Wyeth will suggest a title, such as "Director," that designates the manager of an accrediting authority and is consisent from State to State. Bob Wyeth will e-mail the suggestion to John Anderson.	
6	John Anderson will provide a schedule for future teleconferences to teleconference participants by e-mail.	
7	John Anderson and Jeri Long will review the Robinson/Flowers list of deviations from ISO Guide 58 and will make professional judgments about the incorporation of ISO Guide 58 into Chapter 6. The chapter will be revised accordingly.	

List of Committee Members/Teleconference Participants NELAC Accrediting Authority Committee Teleconference November 14, 1996

Name	Affiliation	Phone/Fax/E-mail
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NELAC ACCREDITING AUTHORITY COMMITTEE TELECONFERENCE MEETING AGENDA

Thursday, November 14, 1996 12:30 PM - 2:30 PM Eastern Standard Time

- -Review of October 23, 1996 meeting minutes
- -Review of Assignments from October 23 teleconference
- -Continue Review of Chapter 6, DRAFT, revision 1, starting at 6.2 (e)